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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,520	12/14/2001	Gene Parunak	10255-018-999	3929

26171 7590 01/11/2005

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,520

Applicant(s)

PARUNAK ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/20/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

This application contains claims 34 and 35 drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Newly submitted claims 36 and 37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The microfluidic device, as recited in claim 1, does not require the incorporation or use of a valve structure, as recited in claims 36 and 37.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 and 37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

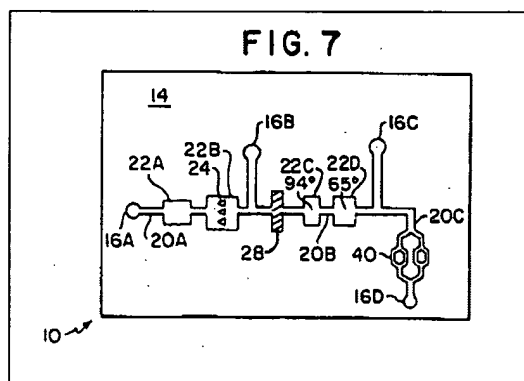
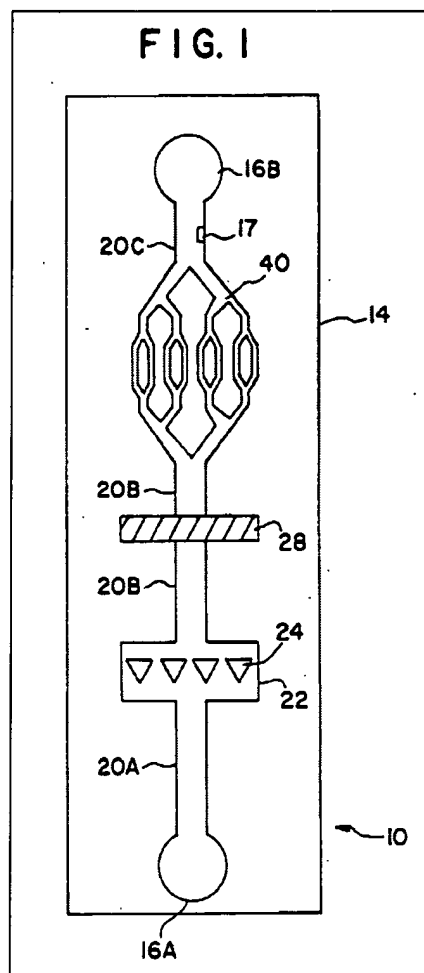
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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1 – 13, 16, 18 – 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (U.S. Pat. No. 5,635,358 A) in view of Brody (U.S. Pat. No. 5,726,404 A). Regarding claims 1 – 3 and 19 – 21, Wilding et al. teach a microfluidic apparatus comprising a flow-through member (e.g., a microfabricated filter 28) and a fluid flow control system incorporating the use of pumps (see col. 3, lines 6 – 10; col. 10, lines 44 – 62; col. 8, lines 52 – 66; figures 1 & 7). The recited “flow-through member” appears to read on a conventional filter, which, as evidenced by Wilding et al., is well known in the art of microfluidics (see MPEP § 2144.03) (see col. 3, lines 6 – 10). The recited “enrichment zone” could simply be construed as the area or volume just before and including the filter where material too large to pass through the filter is retained. Wilding et al. further teach the incorporation of a channel extending downstream from the enrichment zone along a secondary and different pathway, as shown in figure 1 by the fractal detection region (40) comprising the indicated channel network. Wilding et al. do not specifically teach the incorporation of a gas actuator system or pressure control means for providing fluid flow control within a microfluidic system. However, gas actuated fluid flow control systems for microfluidic devices are well known in the art, as is evidenced by Brody (see col. 4, lines 32 – 67; col. 6, lines 57 – 60). Hence, a person of ordinary skill in the art would accordingly have recognized the functional equivalence of these two fluid flow mechanisms within microfluidic devices (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532

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(CCPA 1982). Furthermore, a person of ordinary skill in the art would have recognized the suitability of using a gas actuated mechanism within a microfluidic apparatus for the same intended purpose of facilitating sample fluid flow control within the microfluidic apparatus (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a gas actuated pumping mechanism to facilitate sample fluid movement, as taught by Brody, with the Wilding et al. microfluidic apparatus, in order to facilitate effective sample fluid transfer and processing within the apparatus. The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).



Regarding claims 4 and 22, Wilding et al. teach the incorporation of a downstream region (e.g., 20C or 16B). Regarding claims 5 – 7, 23 and 24, Wilding et al. teach the incorporation of valves to control fluid flow within the apparatus, such as through ports 16C and 16D (see col. 10,

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lines 10 – 67). In addition, with respect to the functional recitations of claims 7, 24 and 26, the applicant is advised that the Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Regarding claims 8, 10, 25 and 33, Wilding et al. teach that each of the components (i.e., mesoscale flow channel 20, cell lysis chamber 22, and fractal detection region 40, etc.) of the microfluidic apparatus are integral to a silicon substrate (14) (see col. 8, lines 52 – 66; figures 1 & 2). Furthermore, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Therefore, it would have been obvious to a person of ordinary skill in the art to integrate each of the functional components of the microfluidic apparatus within a silicon substrate.

Regarding claim 9, this claim recites a functional limitation attributed to the gas actuator of the microfluidic apparatus, as taught by Wilding et al. in view of Brody. The applicant is advised that the Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable

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from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Regarding claims 11 and 12, Wilding et al. teach the incorporation of a mixing zone (section 22D) (see col. 10, lines 44 – 62; figure 7).

Regarding claim 13, Wilding et al. teach the incorporation of a lysing zone (22) (see figure 1).

Regarding claims 12, 13 and 27 – 29, the applicant is advised that these claims recite process or intended use limitations (i.e., what is processed by the claimed apparatus, such as the particle sample or liquid), which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

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Regarding claims 16 and 32, Wilding et al. teach that the apparatus is utilized in performing PCR (see col. 1, lines 19 – 33; col. 10, lines 10 – 62).

Regarding claim 18, Wilding et al. teach a fluid source channel (e.g., 20A, 16A) in fluid communication with the enrichment zone (see figure 1).

Regarding claim 30, Wilding et al. teach the incorporation of a positioning element for lysing (24) in lysing zone (22) (see figure 1).

2. Claims 14, 15, 17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. and Brody, as applied to claims 1 – 13, 16, 18 – 30, 32 and 33 above, and further in view of Tai et al. (U.S. Pat. No. 6,534,295 B2). Wilding et al. do teach the incorporation of a lysing zone (cell handling region 22) (see col. 6, lines 30 – 49; figure 1). Wilding et al. and Brody do not specifically teach the incorporation of an electrical field-based cell lysing mechanism within the microfluidic apparatus or a method step employing the use of such a lysing mechanism. However, Tai et al. do teach a micromachined cell lysis device based upon the application of pulsed electric fields (see col. 2, lines 31 – 67). Both of the cell lysing mechanisms disclosed by Wilding et al. and Tai et al. are notoriously well known in the art for being utilized for the same intended purpose, for the lysis of cell-containing samples within microfluidic devices. Hence, these cell lysis mechanisms are considered functional equivalents clearly recognized by a person of ordinary skill in the art (see MPEP § 2144.06). Therefore, a person of ordinary skill in the art would have recognized the suitability of using an electrode-based cell lysis device within a microfluidic apparatus for the same intended purpose of facilitating cell lysis (see MPEP § 2144.07). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a

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substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the teachings of Tai et al. regarding the use of a micromachined electrical field-based cell lysis device with the Wilding et al. microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to provide a micromachined electric field-based cell lysing mechanism, as taught by Tai et al., with the microfluidic apparatus of Wilding et al. and Brody in order to facilitate effective cell lysing and subsequent analysis. Regarding claim 15, Wilding et al. teach the use of a positioning element, such as a pump, for effecting fluid transfer through the microfluidic device (see col. 8, lines 46 – 66; col. 9, lines 6 – 23).

Regarding claim 17, Wilding et al. teach that each of the functional components (i.e., mesoscale flow channel 20, cell lysis chamber 22, and fractal detection region 40, etc.) of the microfluidic apparatus are integral to a silicon substrate (14) (see col. 8, lines 52 – 66; figures 1 & 2). Furthermore, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Therefore, it would have been obvious to a person of ordinary skill in the art to integrate each of the functional components of the microfluidic apparatus within a silicon substrate.

Response to Arguments

1. Regarding the rejection of claims 18 and 27 under 35 U.S.C. 112, second paragraph as being indefinite, applicants arguments and amendments are persuasive. This rejection is withdrawn.
2. Regarding the rejection of claims 1 – 13, 16, 18 – 30, 32 and 33 under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (U.S. Pat. No. 5,635,358 A) in view of Brody (U.S. Pat. No. 5,726,404 A), applicants arguments and amendments are not persuasive. This rejection is maintained. The applicant essentially argues that the prior art does not teach the claimed apparatus. However, as discussed above, the positively recited structural limitations of the claimed apparatus still read on the apparatus taught by Wilding et al. in view of Brody. The applicant further argues that the gas actuation system as recited in the pending claims is not taught by the prior art. However, Wilding et al. do teach that a fluid sample is applied to an inlet port of the microfluidic apparatus and a pump is actuated to force the sample through the flow system of the microfluidic apparatus (see col. 3, lines 41 – 51). Wilding et al. do teach the use of a flow-through member or microfabricated filter prior to analysis for the presence of an intracellular analyte (see col. 3, lines 1 – 10). The microfabricated filter would essentially serve the function of concentrating or enriching the sample with the target intracellular analyte by further removing the other constituents, such as cellular debris. As discussed above, the incorporation of a gas actuation or pressure control means, as disclosed by Brody, in substitution of the functionally equivalent pump means, as disclosed by Wilding et al., would have been within the ambit of a person of ordinary skill in the art. Furthermore, as evidenced by Brody and discussed above, a person of ordinary skill in the art would accordingly have had a

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reasonable expectation for success of incorporating a gas actuation system or pressure control means within a microfluidic device for facilitating effective fluid flow control (see col. 4, lines 32 – 45). The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Furthermore, regarding claims drawn to an apparatus or product statutory class of invention, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to modify the analytical microfluidic apparatus of Wilding et al. to incorporate a gas actuation or pressure control-based system, as disclosed by Brody, to provide for the claimed invention having effective fluid flow control.

3. Regarding the rejection of claims 14, 15, 17 and 31 under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. and Brody, as applied to claims 1 – 13, 16, 18 – 30, 32 and 33 above, and further in view of Tai et al. (U.S. Pat. No. 6,534,295 B2), applicants arguments and amendments are not persuasive. This rejection is maintained. The applicant essentially argues that the prior art does not teach the claimed apparatus. However, as discussed above, the positively recited structural limitations of the claimed apparatus still read on the apparatus taught by Wilding et al. in view of Brody and Tai et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

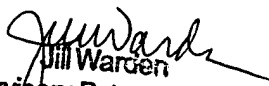
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
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Technology Center